

- ☒ Petition for one (1) month(s) extension of time pursuant to 37 C.F.R. §§ 1.17 and 1.136(a). \$110.00 for the extension of time.
- ☐ No fee is required.
- ☒ Check(s) in the amount of \$110.00 is(are) enclosed.
- ☐ Please charge Deposit Account No. 02-2448 in the amount of \$0.00. This form is submitted in triplicate.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By M.A. Csm
Gerald M. Murphy, Jr., #28,977

MaryAnne Armstrong, PhD., #40,069

GMM/MAA/csm
0230-0161P

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Attachment(s)

(Rev. 09/30/02)



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BOX AF
REPLY UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1651
PATENT
0230-0161P

IN THE U.S. PATENT AND TRADEMARK OFFICE

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AUG 22 2003

TECH CENTER 1600/2900

Applicant: Kenji ASANO et al. Conf.: 3333
Appl. No.: 09/856,718 Group: 1651
Filed: May 25, 2001 Examiner: S. Coe
For: LAK ACTIVITY ENHANCES DERIVED FROM EXTRACT OF
LENTINUS EDODES MYCELIUM AND LAK ACTIVITY-ENHANCING
FORMULATIONS CONTAINING THE EXTRACT

REPLY UNDER 37 C.F.R. §1.116

Assistant Commissioner for Patents
Washington, DC 20231

April 17, 2003

Sir:

In response to the Office Action issued December 17, 2002, the due date having been extended for one (1) month to April 17, 2003, the following remarks are respectfully submitted.

REMARKS

Rejections under 35 U.S.C. §102

Claims 1, 2, 4-10, 12, 13 and 15-20 having been rejected under 35 U.S.C. §102 as being anticipated by U.S. Pat. No. 4,461,760. The Examiner points to column 2, line 48 through column 3, line 5 as teaching the method recited in claim 1 for isolating a composition. The Examiner asserts that since the

'760 patent teaches administering the same product to the same patient LAK activity would inherently be enhanced.

The "Example" that begins in column 2 of the '760 patent teaches a preparation process that includes the following steps:

- 1) culturing *L. edodes* mycelia on a solid medium of bagasse and rice bran (column 2, lines 48 and 49);
- 2) crushing the solid medium with the mycelium (column 2, lines 58-60);
- 3) adding water;
- 4) digesting the preparation with enzymes such as cellulase, glucosidase and protease, in the mixture (column 3, lines 1-2); and
- 5) raising the temperature to inactivate the enzymes (column 3, line 4).

The present invention, as encompassed by claim 1, on the other hand is drawn to a LAK activity enhancer containing an extract of *Lentinus edodes* mycelium, which is prepared by

preparing a suspension by crushing and delignifying a solid medium containing *Lentinus edodes* mycelia in the presence of water and one or more additive enzymes selected from the group consisting of cellulase, protease and glucosidase, wherein the solid medium is based on bagasse and defatted rice bran; and

raising the temperature of the suspension to about 80-100°C to inactivate the enzymes. Claims 12 and 19 are drawn to methods of using a LAK activity enhancer prepared in accordance with the recited method and claim 20 is drawn to the method of preparing the LAK activity enhancer.

Thus, the present invention requires that in the preparation of the LAK activity enhancer the suspension is prepared by crushing and delignifying a solid medium containing *Lentinus edodes* mycelia in the presence of one or more additive enzymes, i.e. the enzymes used in preparing the LAK activity enhancer of the invention are exogenously added to the preparation.

With the process used in the '760 patent the cellulase, protease and glucosidase are not exogenously added, but rather originate from the nutrient medium and tissue-medium. See column 3, lines 1-3.

This difference between the preparation method of the present invention and the method of the '760 patent of using exogenously added enzymes (invention) versus enzymes present in the medium ('760 patent) results in a different end product.

As discussed previously, the extract of the present invention prepared from *Lentinus edodes* mycelium in accordance with the recited method contains approximately 40% glucose as a primary component. The preparation of the '760 patent, on the other hand, contains primarily xylose as a primary component (LAP-1: 39.0% xylose and LAP-2:30.4% xylose). The differences in the sugar components of the invention versus that of the preparations of the '760 patent are believed to result from differences in the methods of preparation, i.e. using exogenously added enzymes (additive enzymes) with the invention, versus endogenous enzymes found in the medium in the '760 patent.

Thus, the extract of the present invention of claim 1, due to the recited method of production, is distinct from that of U.S. '760 and the present invention is not anticipated by the reference. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1-5, 7, 8, 12, 14 and 18 have been rejected under 35 U.S.C. §103 as being obvious over U.S. '760. The Examiner asserts that U.S. '760 differs from the present invention in the

administered and the amounts, but that the forms are well-known and the determination of the dosage is routine optimization. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

As discussed above, the extract of the present invention is different from the extract of the '760 patent due to the recited method of preparation. There is no suggestion in the '760 patent of the presently recited extract or required recited the method for obtaining extract, which results in the distinct product. As such, the present invention is not obvious over U.S. '760 and withdrawal of the rejection is respectfully requested.

As the above amendments and remarks address and overcome the rejections, withdrawal thereof and allowance of the claims are respectfully requested.

Should the Examiner have any questions regarding the present application, she is requested to please contact MaryAnne Armstrong, PhD (Reg. No. 40,069) in the Washington DC area at (703) 205-8000.

Applicants request a one (1) month extension of time for filing the present response. The required extension fee is attached hereto.

Appl. No. 09/830,449

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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